

REMARKS

Claims 39 and 44-47 are now pending and stand rejected in the application. No claim amendments are offered. Claims 39 and 44-47 remain pending.

REJECTION UNDER 35 U.S.C. § 103

Claims 39 and 44-47 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over the Harper reference (WO00/44375) in view of the Hamilton reference (U.S. Pat. No. 6,335,361). The applied references have been the subject of extensive discussion by both Applicant and Examiner. For the reasons discussed below, Applicants respectfully submit that the references when combined do not contain all the limitations of the current claims. Accordingly, Applicants respectfully traverse the rejection and request reconsideration.

Combination of two references to support an obviousness rejection of claims is appropriate where there is a motivation or an "apparent reason" to so combine them. Even when motivation for the combination is present, however, the combination does not make the claims obvious unless the combined references contain each and every limitation and element of the rejected claims. When considering what the combined references teach, it is appropriate to read the references as a whole in light of the meaning that a person of skill in the art would give to their disclosure. Also, in considering whether the combined references anticipate or make obvious the claims, it is appropriate to consider each and every element of the claims, including those aspects that are described in the specification and supported by experimental or other

evidence. With these principles in mind, Applicants offer the following comments on the rejection and the current state of the claims.

The Harper reference discloses feeding dog and cat food that contains vitamin E and vitamin C together. In Example 15, an antioxidant fortified diet is fed to cats. A complete wet diet is supplemented with an antioxidant cocktail containing vitamin E, vitamin C, β -keratin, lutein, taurine, and lycopene. Tests for antioxidant capacity demonstrate that cats receiving the cocktail had increased antioxidant capacity. It was said that the antioxidant fortified diet "confers an increased ability to mitigate the deleterious effects associated with oxidative insult."

Similarly, in Example 17, dogs were fed a standard diet supplemented with an antioxidant cocktail containing α -tocopherol (vitamin E), ascorbate (vitamin C), β -keratin, lutein, and taurine. Antibody levels to vaccine antigens were measured and the results were said to indicate that "the antioxidant cocktail has a highly beneficial effect on the immune response of young animals." Similarly, Example 18 gives results of feeding the dog diet to adult and senior dogs.

The diets fed in Harper are said to provide "a means to overcome the problem of oxidative stress in the domesticated cat and dog." Page 1, lines 14-15. As discussed in Harper, the concept of "oxidative stress" is a nebulous one and seems to refer to anything caused by or associated with the presence of free radicals in a living organism. For example, the first paragraph states that "if free radical production and removal is not controlled, then their affects on an organism can be damaging." It is therefore a goal of Harper to reduce such "oxidative stress, which is said to "in particular strengthen[] the immune response and provide[] a healthier animal." Page 2, lines 25-26.

Strengthening the immune response is consistent with the data in Examples 17 and 18 discussed above. Harper further describes oxidative stress at page 13 beginning at line 7. Specifically, oxidative stress is said to be a component of a "disease or disorder such as ageing, cancer, heart disease, atherosclerosis, arthritis, cataracts, inflammatory bowel disease, renal disease, renal failure, neurodegenerative disease and immunity". Such a list is consistent with the wide ranging scope of the disclosure of Harper, and that it is directed toward anything in the body that might have to do with free radicals.

The Harper reference does not teach that its methods of reducing "oxidative stress" would provide a method for inhibiting the loss of learning ability in an aged companion pet or for increasing the aged companion pets learning ability, as recited in the currently rejected claims. Certainly, Applicants concede that the loss of learning ability may be associated with one or more of the disorders listed on page 13 of the Harper reference. For example, aging in humans (and presumably in pets) is often associated with a decline in mental facilities that include learning ability. And, as discussed in previous prosecution, neurodegenerative disease might also be associated with a loss of learning ability or the desire to increase the learning ability of an aged individual. Nevertheless, enhancing learning ability is not specifically mentioned in Harper and no data or examples is given where any diet fed to cats or dogs resulted in increased learning ability.

Turning now to the secondary (Hamilton) reference, that reference discloses compositions containing both carnitine and α -lipoic acid, which are given to humans combat "benign forgetfulness" or memory loss, especially in older people. The reference even mentions in passing that the combination of carnitine and α -lipoic acid

"is provided in pet formulations" so that dogs and cats are "expected to benefit from the composition." Column 11, lines 9-13. Presumably, the benefit afforded to dogs and cats in this passage would be the same as those provided in humans administered the composition, mainly overcoming difficulties in memory.

As a preliminary matter, Applicants would like to point out that the Hamilton reference also fails to teach or suggest any use of compositions to inhibit the loss of learning ability of an aged companion pet as recited in the rejected claims. Again, Applicants do not deny that difficulties in memory can conceivably be associated with loss of learning ability. But not all memory difficulties cause loss of learning ability, and removing memory difficulties by treatment does not necessarily cure the memory difficulties. It is crystal clear that overcoming difficulties in memory as taught in Harper and increasing the learning ability of an aged companion pet as recited in the rejected claims are not the same.

Moreover, the teachings of the Hamilton reference are overwhelmingly addressed to treatments of humans and not to aged companion pets as recited in the current claims. Thus, at column 1, lines 18-21:

"Many adults gradually develop noticeable difficulties in memory, at first for names, then for events, and sometimes even occasionally for special relationships."

And at column 1, line 62 to column 2, line 1:

"In brief, the criteria of AMMI [age associated memory impairment] include the presence of subjective memory decline...and the absence of dementia...in a person age 50 years or older."

An object of the invention is said to be

"...to prevent and ameliorate the cognitive deficits which occur in a variety of other disorders associated with impaired metabolism

of the brain, including stroke, traumatic brain injury, toxic exposure, and Type II Diabetes Mellitus."

It is evident that the disorders considered in the above quote are those that occur in humans.

Further, column 9, line 50 to column 10, line 8, discloses adding carnitine and α -lipoic acid to a variety of human food, such as cereals, pastries, milk products, sport drinks, diet drinks, and the like. The rest of the reference is replete with descriptions of administering carnitine and α -lipoic acid to humans to "discourage age related memory loss", column 7, lines 14-15; "To restor[e] ... age related mitochondria function and metabolic activity in individuals in which those were compromised. Column 8, lines 8-10; and so on. In this light, the daily dosages of carnitine and α -lipoic acid as suggested in the reference are understood to reply to doses for humans. See for example, column 8, lines 37-42.

The person of skill in the art would thus read the Hamilton reference to be directed to treatment regimens for human beings and not for pets, notwithstanding that one paragraph of the disclosure at column 10, lines 9-16, seems to suggest giving carnitine and α -lipoic acid to animals. In light of the minimal teaching of administering the composition to animals, Applicants respectfully submit that even the suggestion at column 10, lines 16-22 to supplement the diet of "older individuals" with calcium and vitamins such as vitamin C and vitamin E would be understood to refer to giving them to human subjects, and not to pets such as dogs and cats.

Finally, even if the reference could be read as suggesting to provide dogs and cats with a diet containing carnitine, α -lipoic acid, and additional vitamins, the reference still does not suggest treating an aged pet for the purpose of inhibiting the loss of

learning ability or for increasing the pet's learning ability. As mentioned above, the Hamilton reference is drawn exclusively to treatment of "difficulties in memory" and is overwhelmingly directed, in the eyes of those of skill in the art, toward treatment of humans.

The current claims recite that a mixture of antioxidants that includes vitamin E, vitamin C, and one or both of α -lipoic acid and carnitine are used in a method of inhibiting the loss of learning ability or for increasing the learning ability of an aged companion pet in need of such treatment. As developed above, the treatment is not being claimed for a broad ill defined category such as oxidative stress (as in Harper) or for the narrow but separate symptom of forgetfulness (as in Hamilton). Rather, the treatment is claimed to be useful for a specific purpose in specific animals. The treatment and results are illustrated in the Examples of the current specification.

In Example 1, a control group was fed a diet that contained low levels of vitamin E and vitamin C. A test group received a diet containing higher levels of vitamin E and vitamin C, and containing in addition 260 ppm L-carnitine and 135 ppm α -lipoic acid. A "highly significant difference" between the two groups was reported in the landmark discrimination learning tasks, as described on page 8, lines 12-20 of the specification. This result shows the effectiveness on the diet in providing a method for increasing the learning ability of the pets.

Likewise in Example 2, Beagles were tested for their ability to learn a size discrimination task. Diet No. 1 included high levels of vitamin E, vitamin C, L-carnitine, and α -lipoic acid. Diet No. 3 contained low levels of vitamin E and vitamin C, along with

low levels of L-carnitine and no α -lipoic acid. The diet was found to have a significant overall effect on the scores in the learning test.

Based on the above discussion, Applicants respectfully submit that the Harper and Hamilton references when combined do not lead the person of skill in the art to the subject matter of the current claims. As discussed, those claims recite methods for increasing learning ability of aged companion pets by feeding them a diet including vitamin C, vitamin E, carnitine, and α -lipoic acid. Significantly, the claim also recites adding the mixture of oxidants "at levels sufficient to accomplish the said inhibiting or increasing". As elaborated above, the references do not disclose any diets or methods that specifically increase the learning ability of an aged pet, and do not provide any guidance to the person of skill in the art to administer the antioxidants at "levels sufficient" to increase the learning ability or inhibit the loss of learning.

The teachings of the references must be read in light of the understanding of the person of skill in the art. The combined references must teach or suggest each and every limitation of the claims. The claims recite methods for increasing the learned ability of an aged pet by giving them antioxidants at levels sufficient to provide such effect. The references do not disclose increasing the learning ability of a pet and provide no guidance for accomplishing it with the combination of antioxidants, while the Examples of the current specification demonstrate the effectiveness of the claimed method at improving learning ability of companion animals. For all of the above reasons, Applicants respectfully submit that a *prima facie* case of obviousness is not made out in light of the two references. Accordingly, Applicants respectfully request that the rejection be withdrawn.

CONCLUSION

For the reasons discussed above, Applicants respectfully submit claims 39 and 44-47 are in allowable state and respectfully request an Early Notice of Allowance. The Examiner is invited to telephone the undersigned if that would be helpful to resolving any issues.

Respectfully submitted,

Dated: October 1, 2007

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